

Claims

1. A method for assessing the performance of a system for delivering a pharmaceutical agent to a portion of a body of a host comprising the steps of:

applying an electrode configuration to the portion of the body;

infusing the portion of the body with the pharmaceutical agent;

electrically stimulating the portion of the body using a signal generator coupled to the electrode, the signal generator being operable to deliver an at least partially periodic signal to the electrode; and,

measuring and recording a voltage and current delivered to the portion of the body while electrically stimulating the portion of the body thereby generating electrical parameter data.

2. The method of claim 1, wherein the electrode configuration comprises a plurality of individual conductors.

3. The method of claim 1 further comprising:
measuring an immune system response; and
correlating the immune system response with the electrical test data whereby the performance of the system for delivering said agent can be assessed.

4. The method of claim 1 further comprising:
measuring a transgene expression level; and
correlating the transgene expression level with the electrical test data whereby the performance of the system for delivering said agent can be assessed.

5. An electrical stimulation electrode apparatus for delivering an electrical stimulation treatment to a portion of a body of a host at best comprising at least a pair of electrodes each having a conductive body portion, and partially conductive coating applied to a surface of the conductive body portion.

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6. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating has an impedance in the range of $1K\Omega$ to $10M\Omega$.

7. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating comprises at least one of PFA and Ryton.

8. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating comprises at least one of PFA and Ryton and a conductive material comprising at least one of carbon black, graphite and metal powder.

9. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating is at least partially formed of enamel paint.

10. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating is at least partially formed of enamel paint and a clear top coat.

11. The electrical stimulation electrode apparatus of claim 5 wherein the partially conductive coating is discontinuous over isolated portions of a surface thereof positioned for contact with the portion of the body.

12. An electrical stimulation apparatus for delivering an electrical stimulation treatment to a portion of a body of a host comprising a signal generator having an output, and at least a pair of electrodes coupled to the output of the signal generator, each electrode having a conductive body portion, and a partially conductive coating applied to a surface of the conductive body portion.

13. The apparatus of claim 12 wherein the signal generator has an arbitrary waveform signal generator for generation of signals of any shape in time and a signal amplifier configured in one of a constant current and constant voltage feedback mode.

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14. The apparatus of claim 12 further comprising an injecting needle and a needle/electrode holder with a plurality of angular guide holes for guiding the needle and electrodes into the proper orientation with respect to the portion of the body.

15. A method for delivering a pharmaceutical agent to a portion of a body of a host comprising the steps of:

applying at least one electrode to the portion of the body, said electrode having a partially conductive outer surface;

infusing the portion of the body with the pharmaceutical agent;

electrically stimulating the portion of the body using a signal generator coupled to the electrode, the signal generator being operable to deliver an at least partially periodic signal to the electrode.

16. The method of claim 15 further comprising the steps of applying at least two electrodes to the portion of the body, each electrode having a partially conductive outer surface and wherein the portion of the body is electrically stimulated using a signal generator coupled to each electrode, the signal generator being operable to deliver an at least partially periodic signal to the electrodes.

17. The method of claim 16 wherein the signal generator is operated in a constant voltage mode.

18. The method of claim 15 wherein the signal generator is operable to deliver about ± 100 to ± 400 volts.

19. The method of claim 15 wherein the signal generator is operable to deliver a charge in the range of 5-20 millicoulombs to the portion of the body per periodic cycle.

20. An electrical stimulation apparatus for delivering an electrical stimulation treatment to a portion of a body of a host comprising a first signal generator having an output, and at least

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applying at least a pair of electrodes to a portion of the tissue, said portion having an electrical resistance;

controlling a current between the electrodes so as to deviate from a current level said voltage would produce in the tissue at said voltage difference under Ohm's law.

23. The method of claim 21, wherein the current is limited by providing a discontinuous barrier between at least a portion of the electrodes and the tissue.

24. The method of claim 23, wherein at least one of the electrodes comprises a sharpened point and wherein the current is limited by a material that is discontinuous at the point.

25. A method of electrically stimulating the cellular delivery of a pharmaceutical agent *in vivo* within a mammalian tissue, which comprises:

applying an electrode configuration to a portion of the mammal, wherein said electrode configuration having a partially conductive outer surface or 2 sets of complementary electrodes;

infusing the portion of the mammal with a pharmaceutical agent; and,

establishing an electric field of a predetermined potential between the electrode configuration such that the current from the electric field is limited to an amplitude that is less than the current that would be predicted to flow under Ohm's law; wherein establishing the electric field and current flow occurs without significant involuntary muscle reflexes during the course of treatment.

26. The method of claim 25 wherein the pharmaceutical agent is a nucleic acid molecule.

27. The method of claim 25 wherein the nucleic acid molecule is a DNA plasmid expression vector.

28. The method of claim 25 wherein the mammal is a human.

29. The method of claim 25 wherein the pharmaceutical agent is a nucleic acid molecule.

30. The method of claim 29 wherein the nucleic acid molecule is a DNA plasmid expression vector.

31. The method of claim 25 wherein the pharmaceutical agent is a protein.

32. The method of claim 25 wherein the pharmaceutical agent is an organic molecule.

33. A method of electrically stimulating the cellular delivery of a pharmaceutical agent *in vivo* within a mammalian tissue, which comprises:

applying an electrode configuration to a portion of the mammal, wherein said electrode configuration having a partially conductive outer surface or 2 sets of complementary electrodes;

infusing the portion of the mammal with a pharmaceutical agent;

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establishing an electric field of a predetermined potential between the electrode configuration such that the current from the electric field is limited to an amplitude that is less than the current that would be predicted to flow under Ohm's law; and,

measuring and recording a voltage and current delivered to the portion of the mammal while electrically stimulating to portion of the mammal thereby generating electrical parameter data,

wherein establishing said electric field comprises applying electric stimulus without measurable involuntary muscle reflexes during the course of treatment.

34. The method of claim 33 wherein the pharmaceutical agent is a nucleic acid molecule.

35. The method of claim 34 wherein the nucleic acid molecule is a DNA plasmid expression vector.

36. The method of claim 33 wherein the mammal is a human.

37. The method of claim 36 wherein the pharmaceutical agent is a nucleic acid molecule.

38. The method of claim 37 wherein the nucleic acid molecule is a DNA plasmid expression vector.

39. The method of claim 33 wherein the pharmaceutical agent is a protein.

40. The method of claim 33 wherein the pharmaceutical agent is an organic molecule.

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